



H-A-

0300

0400

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

is re application of

Wolfgang HEIL et al.

Serial No.: 09/757,688

Filed: January 11, 2001

For: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

:

:

:

:

Group Art Unit: Unknown

Examiner: Unassigned

SUPPLEMENTAL PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Further to our Preliminary Amendment filed February 23, 2001, please amend the above-identified application as follows:

In the Claims:

Please revise claims 77, 81, 89, and 94 as follows:

77. (Amended) A pharmaceutical composition comprising

as a first active agent, an estrogen (or naturally or synthetic derivative thereof) in sufficient amounts to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women, and

as a second active agent, 6 β ,7 β ;15 β ;16 β -dimethylene-3-oxo-17 α -preg-4-ene-21,17-carbolactone (drospirenone) in sufficient amounts to protect the endometrium from the adverse effects of estrogen,

together with a pharmaceutically acceptable excipient or carrier.

81. (Amended) A composition according to claim 77, wherein the estrogen is selected from the

09757688-032904

group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17 β -estradiol sulfate, 17 α -estradiol sulfate, equilin sulfate, 17 β -dihydroequilin sulfate, 17 α -dihydroequilin sulfate, equilenin sulfate, 17 β -dihydroequilenin sulfate and 17 α -dihydroequilenin sulfate or mixtures thereof.

89. (Amended) A pharmaceutical composition comprising

as a first active agent estradiol in amounts corresponding to a daily dose of 1 to 3 mg to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women,

and as a second active agent 6 β ,7 β ;15 β ;16 β -dimethylene-3-oxo-17 α -preg-4-ene-21,17-carbolactone (drospirenone) in amounts corresponding to a daily dose of 1 to 3.5 mg to protect the endometrium from the adverse effects of estrogen, together with a pharmaceutically acceptable excipient or carrier.

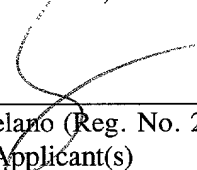
94. (Amended) A method according to claim 90, wherein the estrogen is selected from the group consisting of estrogen is selected from the group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17 β -estradiol sulfate, 17 α -estradiol sulfate, equilin sulfate, 17 β -dihydroequilin sulfate, 17 α -dihydroequilin sulfate, equilenin sulfate, 17 β -dihydroequilenin sulfate and 17 α -dihydroequilenin sulfate or mixtures thereof.

REMARKS

The Preliminary Amendment filed February 23, 2001, inadvertently omitted the α and β symbols due to clerical error. The amendments are not new matter.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,



Anthony J. Zelano (Reg. No. 27,969)
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Boulevard, Suite 1400
Arlington, Virginia 22201
Direct Dial: (703) 812-5311
E-mail Address: zelano@mwzb.com

Date: March 29, 2001

09757688-032904
T062E0-8897560



VERSION WITH MARKINGS TO SHOW CHANGES MADE

77. (Amended) A pharmaceutical composition comprising

as a first active agent, an estrogen (or naturally or synthetic derivative thereof) in sufficient amounts to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women, and

as a second active agent, $6\beta,7\beta;15\beta;16\beta$ -dimethylene-3-oxo- 17α -preg-4-ene-21,17-carbolactone (drospirenone) in sufficient amounts to protect the endometrium from the adverse effects of estrogen,

together with a pharmaceutically acceptable excipient or carrier.

81. (Amended) A composition according to claim 77, wherein the estrogen is selected from the group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17β -estradiol sulfate, 17α -estradiol sulfate, equilin sulfate, 17β -dihydroequilin sulfate, 17α -dihydroequilin sulfate, equilenin sulfate, 17β -dihydroequilenin sulfate and 17α -dihydroequilenin sulfate or mixtures thereof.

89. (Amended) A pharmaceutical composition comprising

as a first active agent estradiol in amounts corresponding to a daily dose of 1 to 3 mg to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women,

and as a second active agent $6\beta,7\beta;15\beta;16\beta$ -dimethylene-3-oxo- 17α -preg-4-ene-21,17-carbolactone (drospirenone) in amounts corresponding to a daily dose of 1 to 3.5 mg to protect the endometrium from the adverse effects of estrogen,
together with a pharmaceutically acceptable excipient or carrier.

94. (Amended) A method according to claim 90, wherein the estrogen is selected from the group consisting of estrogen is selected from the group consisting of estradiol, estradiol sulfamates, estradiol valerate, estradiol benzoate, ethinyl estradiol, estrone, estriol, estriol succinate and conjugated estrogens, including conjugated equine estrogens such as estrone sulfate, 17β -estradiol sulfate, 17α -estradiol sulfate, equilin sulfate, 17β -dihydroequilin sulfate, 17α -dihydroequilin sulfate, equilenin sulfate, 17β -dihydroequilenin sulfate and 17α -dihydroequilenin sulfate or mixtures thereof.

09757688 032901